

### **REMARKS**

Claims 1-23 are pending in this application. By this Amendment, claims 1, 16 and 23 are amended. Support for the amendments can be found throughout the present specification. See, for example, page 5, line 6, and page 21, line 16. No new matter is added.

Applicant thanks the Examiner for the courtesies extended during a July 22, 2004, telephonic interview with Applicant and his undersigned representative, during which the outstanding rejections of record and the above amendments were discussed. The remainder of Applicant's separate record of the substance of the interview is contained in the remarks below.

#### **Section 112, Second Paragraph, Rejection**

The Office Action also rejects claims 1-23 under 35 U.S.C. 112, second paragraph, as being indefinite for containing asserted informalities. As agreed during the July 22, 2004, telephonic interview, this rejection is overcome with the above amendments to the claims. Reconsideration and withdrawal of the rejection of claims 1-23 under 35 U.S.C. 112, second paragraph, are respectfully requested.

#### **Section 103 Rejection**

The Office Action rejects claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Bensadoun et al. (Analytical Biochemistry, Volume 70, pp. 241-250, 1976) taken with Carraro et al. (Biochem. & Biophys. Res. Commun., Vol. 200, No. 2, pp. 916-924, 1994). This rejection is traversed as it may apply to the amended claims.

As Applicant has previously explained, the combination of SDS in Bensadoun's protein would not work. However, in the Office Action, the Examiner asserts that it is necessary for Applicant to provide a side by side comparison showing that using SDS in the Bensadoun et al. method of protein precipitation in dilute solution by mixing the protein solution with an acidic agent would not work.

Applicant has attached hereto a Declaration containing experimental data demonstrating the above. In particular, the Declaration demonstrates that, in the presence of detergent SDS, the method of Bensadoun et al. did not work, as shown in the plot in the Declaration that indicates that no response was achieved (a flat plot), as compared to the quantitative recovery of protein achieved by the present invention.

For at least the above reasons, the presently claimed invention would not have been obvious over the combination of Bensadoun et al. taken with Carraro et al. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-23 under 35 U.S.C. 103(a).

### **Conclusion**

In view of the above amendments and remarks, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly solicited. Should the Examiner believe anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

In the event this paper is not timely filed, Applicant respectfully petitions for an appropriate extension of time. The Commissioner is authorized to charge payment for any additional fees which may be required with respect to this paper to Counsel's Deposit Account 01-2300, referring to client-matter number 108904-00002. Thus, please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300, making reference to Attorney Docket No. 108904-00002.

Respectfully submitted,



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**PATENT APPLICATION**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Aftab ALAM

Art Unit: 1653

Application No.: 09/842,838

Examiner: A. Mohamed

Filed: April 27, 2001

Attorney Dkt. No.: 108904-00002

For: AGENT FOR PROTEIN PRECIPITATION, A METHOD OF PROTEIN  
PRECIPITATION, A METHOD OF PROTEIN ASSAY USING PROTEIN  
PRECIPITATION AGENT, AND A KIT FOR PROTEIN ASSAY

**DECLARATION UNDER 37 CFR §1.132**

**Mail Stop Amendment**

Director for the U.S. PTO

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

I, Dr. Aftab Alam, hereby declare and state:

I am the inventor of the above-referenced invention.

I supervised and/or performed the study described below.

**Side-by-side comparison of Bensadoun & Weinstein Method with the method of  
present invention**

The present specification, at page 2, lines 22-30, and page 10, lines 14-23,  
describes that in the presence of detergent (SDS), Bensadoun and Weinstein does not  
work. The specification cites publications that supports the inventor's statements. The

following data is presented in support of the statements made in the specification. A side-by-side comparison of Bensadoun and Weinstein method was made with the instant invention.

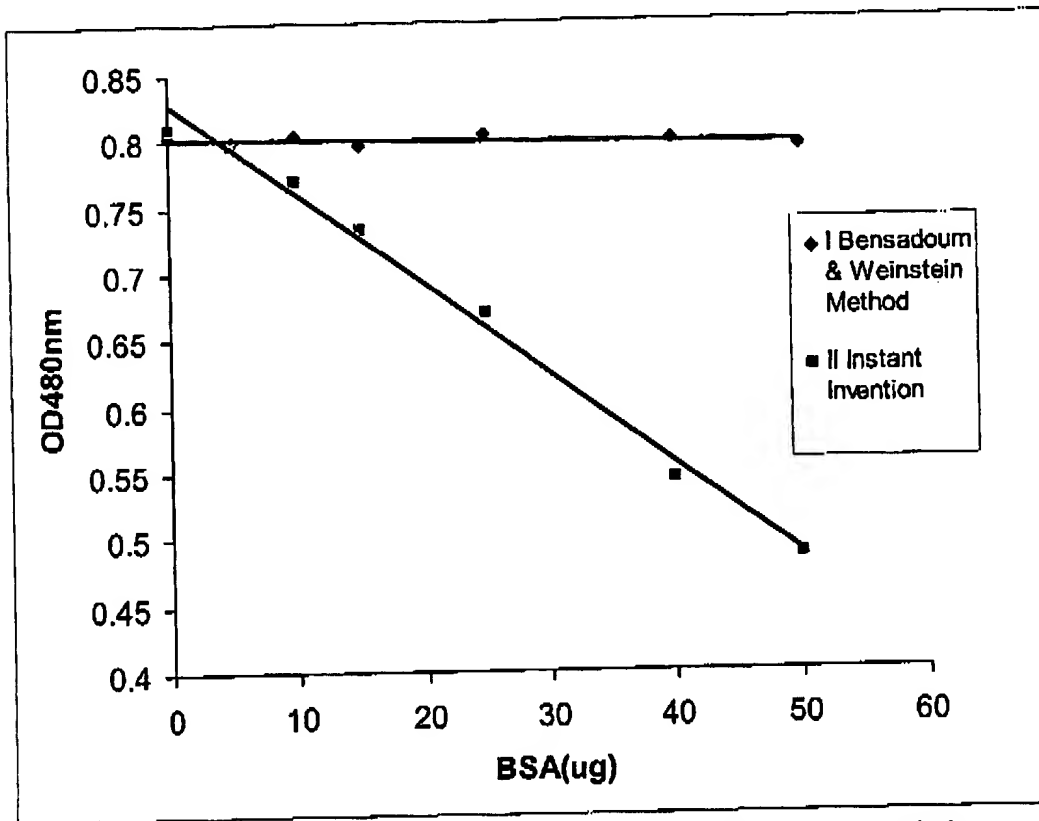
The method of Bensadoun and Weinstein was performed with the exception that a detergent (SDS) was added to the protein solution to a final concentration of 1%. The effectiveness of protein precipitation was measured by protein assay method described in Method and Material section of the specification (Page15-17). In brief, 100µl of alkaline copper solution (1N NaOH containing 0.05% copper sulfate and 0.16% tartrate) was added to each protein precipitate, after mixing, 0.4ml of pure water was added to each tube and mixed. 1.0ml of color producing agent (bathocuproine) was introduced into each tube which produced a characteristic color. The optical density of each tube was determined at 480nm. The optical density of each tube was plotted against the amount of protein added to each tube.

For a side-by-side comparison 0-50µg BSA (50µl) containing 1%SDS was used. For the Bensadoun and Weinstein method 100µg deoxycholate was mixed with each protein sample. TCA solution was added into each sample to a final concentration of 5% TCA. Each tube was centrifuged to collect the precipitated protein pellet. The pellets were subjected to protein assay, as described above.

For the present invention, 0-50µg BSA (50µl) containing 1%SDS was treated according to the invention. Each tube was centrifuged to collect the precipitated protein pellet. The pellets were subjected to protein assay, as described above.

The attached plot shows optical density at various protein amounts for both Bensadoun and Weinstein method (marked as Bensadoun and Weinstein) and the instant invention (marked Instant Invention). The result shows that in the presence of

detergent SDS Bensadoun and Weinstein did not work as the plot did not show any response (a flat plot), whereas the present invention shows quantitative recovery of protein (when the plot is compared with a control, Example 1).



I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Name:

A. Alaw

Date:

July 28, 2004